



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/549,385

06/30/2006

Thorsten Siess

IMPEL.71975

6082

27629 7590 06/25/2009
FULWIDER PATTON LLP
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

06/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/549,385
Filing Date: June 30, 2006
Appellant(s): SIESS ET AL.

Thorsten Siess
Josef Penners
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/31/08 appealing from the Office action mailed 05/14/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

Art Unit: 3763

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

EP 0596172	Fischell et al.	11-1992
20040044266	Siess et al.	4-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3763

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (EP 0596172, cited from IDS) in view of Siess et al. (US 2004/0044266).

Fischell discloses a device comprising a tubular channel 20 and a dilator/coil 12. Fischell further states that the forming the covering/channel 20 so that it fits tightly around the helical coil/dilator 12 would be sliding the coil/dilator 12 through a tube of the plastic (pg 3, lines 27-28). In other words, the coil/dilator 12 is capable or adapted to be retracted from the tube of the plastic or the channel 20; wherein the channel 20 has a wall thickness not larger than 0.06mm and is made from a hard plastic material; the inner diameter of channel is at least as large as the outer diameter of the dilator, (page 3, lines 25-37); wherein dilator and channel comprise a low-friction slip material, such as Teflon. A connecting device 30; the channel 20 comprises a distal end section which at least partly overlaps the distal portion of dilator 12. Fischell does not disclose that the dilator comprises a conical tip portion.

Siess discloses, Figs. 10, a device comprising: a tubular channel 37; a dilator 41 or 18 (Figs. 1-2, 12) comprises a conical tip 44

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Fischell with a conical tip, as taught by Siess, in order to avoid damage to tissue and easier to penetrate and expulse the tissues.

(10) Response to Argument

Applicant argues that:

I) THE SHEATH OF THE PRIMARY REFERENCE IS NOT FORMED EXCLUSIVELY OF PLASTIC:

Applicant argues that the sheath/channel element that is described therein is a metal reinforced structure which is therefore clearly not formed "exclusively of plastic". In the case of the primary reference, the sheath that is described therein is a metal reinforced structured which is therefore clearly not formed "exclusively of plastic".

In response, Fischell clearly discloses that the channel 20 (outer layer) /plastic covering formed of hard plastic material. As noted that, Examiner considers only element 20 as a channel/tubular sheath.

Art Unit: 3763

Examiner is **not** considering the element 12 to be a part of the channel/tubular sheath. Therefore, the metal wire/metallic coil 12 is considered as a dilator but not a part of channel/tubular sheath.

Not only that, the channel made of hard plastic is conventional in the art as Applicant admitted on page 1, line 8 of the Specification.

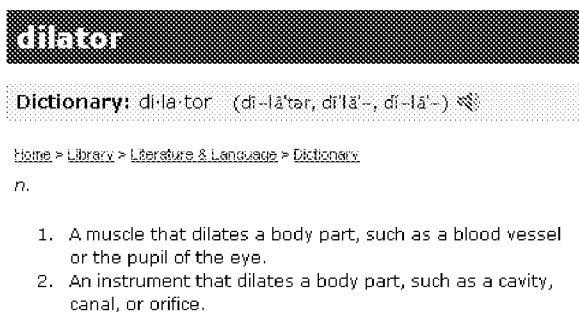
Therefore, the reference of Fischell fully discloses all claimed subject matter as described above.

II) THE REINFORCEMENT COIL OF THE PRIMARY REFERENCE IS NOT A DILATOR AND IS NOT RETRACTABLE:

a. Applicant argues that: Examiner undertakes a hypothetical disassembly of the sheath and then refers to only its outer covering as the “sheath” while characterizing its inner reinforcement coil as a retractable ‘dilator’. This is wholly unreasonable characterization of the structural elements as well as an unreasonable interpretation of the teachings of the reference. Both of reinforcement coil as well as its plastic covering are part and parcel of the sheath.

In response, as Examiner mentioned above that Fischell discloses the tubular channel/sheath 20; the dilator/coil 12. Although Ref Fischell does not explicitly state the words “tubular channel” or “dilator”, however, labels, statements of intended use, or functional language do not structurally distinguish claims over prior art, which can function in the same manner, be labeled in the same manner or be used in the same manner. See *In re Pearson*, *Ex parte Minks*, and *In re Swinehart*.

In this case, the definition of dilator as follows: (get the source from www.answers.com)



Meanwhile, the coil/dilator 12 of Fischell can be read as the definition above. Therefore, the coil 12 of Fischell is considered as a dilator of claimed invention.

Art Unit: 3763

b. Applicant argues that the dilator is not adapted to be retracted from the channel because: the reinforcement coil as well as its plastic covering is part and parcel of the sheath. And the projections into the spaces between adjacent winding of the coil (Figs. 2A-3D) serve to mechanically lock the covering to the coil.

In response, the coil/dilator 12 and the sheath/channel are separate elements (emphasis added). Beside that, Applicant discloses in claim 1 that: the dilator "is adapted to be retracted from the channel".

It has been held that the recitation that an element dilator is "adapted to be retracted from the channel" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

In this case, Applicant only claims that the dilator is "adapted to be retracted from the channel" but does not specifically state the exactly time or when the dilator is adapted to be retracted from the channel. For example: the dilator is adapted to be retracted from the channel in any status (i.e. before or after assembly introduction device or only in the system of introduction device in any times, etc...)

Fischell further states that the forming the covering/channel 20 so that it fits tightly around the helical coil/dilator 12 would be sliding the coil/dilator 12 through a tube of the plastic and then heat shrinking the plastic onto the helical coil (pg 3, lines 27-28). In other words, the coil/dilator 12 is capable or adapted to be retracted from the tube of the plastic or the channel 20 before the step of heat shrinking, therefore, Ref of Fischell is fully covered all claimed invention.

Beside that, the secondary reference, Siess et al. (US 2004/0044266) also discloses the limitation that: a tubular channel 37, the dilator 41 or 18 comprise a conical tip portion 44 and is adapted to be retracted from the channel 37.

Therefore, one skill in the art would be recognized that the modification of Fischell's in view of Siess, in order to avoid damage to tissue and easier to penetrate and expanse the tissues.

c. Applicant states on pg 5 of Appeal brief that:

Art Unit: 3763

In straining to find the claimed structure in the cited reference, the Examiner also completely ignores the teachings of the reference which clearly teach directly away from the concept of an introducer sheath that is readily deformable. Not only is the device referred to in its very title as "non-kinking", but the reliance on the reinforcement coil to prevent the collapse of the sheath is specifically mentioned throughout the specification. The metal reinforcement coil is therefore very much a integral component of the sheath and as such teaches away from a deformable channel, let alone one that is formed exclusively of a thin plastic.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

And furthermore, In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Fischell discloses all claimed subject matter except the dilator tip formed conical tip portion. While, Siess discloses similar device with a tubular channel 37, a dilator 41 or 18 comprises a conical tip 44. Therefore, one skill in the art would recognize that Fischell in view of Siess is reasonable combination.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Art Unit: 3763

/Quynh-Nhu H. Vu/

Examiner, Art Unit 3763

Conferees:

Nick Lucchesi

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761